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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,768	12/21/2004	Fukumi Morishige	122196	4924
25944 7590 12/11/2008 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850				
EXAMINER				
HUGHES, ALICIA R				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
12/11/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/518,768

**Applicant(s)**

MORISHIGE, FUKUMI

**Examiner**

ALICIA R. HUGHES

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 1-9 are pending and the subject of this Office Action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's arguments filed on 05 November 2008 have been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

### ***Claim Rejection - 35 USC § 102***

The following is a quotation of 35 U.S.C. 102(e) which forms the basis for all obviousness rejections set forth in this Office Action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Publication No. 2003-335664 [hereinafter referred to as "Fukumi et al"].

The teachings of Fukumi et al and reference to McFarland et al in this Office's actions of 21 September 2007 and 10 July 2008 are incorporated herein by reference in their entirety.

Applicant now argues (1) that MELAS is a distinctly different disease than presenium encephalopathy or myoclonus syndrome and that the treatment of presenium encephalopathy is an entirely different than the mitochondrial encephalopathy of MELAS; (2) the teachings of myoclonus syndrome in Fukumi et al is irrelevant to the treatment of MELAS, because these are two totally different disorders and the teachings of one disease does not necessarily mean the teaching of the other.

To support the assertion of variation between MELAS and presenium encephalopathy, Applicants only surmise that "the mere fact that both disorders are *types of* encephalopathy does not mean that they are the same disease, that they can or should be treated in the same manner or even that a person having skill in the art would understand them to be related." See page 5 of Applicant's Remarks of 25 September 2008. However, by Applicant's own admission in that statement, both are types of encephalopathy, and thus, are similar and further, the statement that this similarity "does not mean" that they can or should be treated in the same manner is not dispositive of the rejection at hand but is instead but an allegation lacking factual support. Furthermore, by Applicant's own admission, both MELAS and myoclonus syndrome are

mitochondrial diseases and albeit distinct conditions, they are of common etiology. The mere statement of them being different diseases is not in itself dispositive of the teachings in Fukumi et al and again, the statement of irrelevance is but an allegation lacking factual support.

As noted in this Office's previous action, Fukumi et al do essentially anticipate all of the functional claims of the present application. While Fukumi et al do not explicitly purport to treat mitochondrial diseases, inherent in its treatment of, for example, myoclonus syndrome and encephalopathy (See page 2 of 19, paragraph 10) by increasing the bioavailability of L-arginine content, is the treatment of mitochondrial disease (and according to Applicant's specification, MELAS is a mitochondrial disease).. See generally, McFarland, Robert, et al., "The Neurology of Mitochondrial DNA Disease," *Neurology*, Vol. 1, pages 343-351 (October 2002)(noting mitochondrial neurogastrointestinal encephalopathy syndrome, mitochondrial encephalopathy lactic acidosis and stroke-like episodes, and myoclonus epilepsy with ragged red fibres as mitochondrial diseases, and the same are disclosed as treated by the prior art).<sup>1</sup>

In consideration of the foregoing, the instant invention was clearly anticipated by the art disclosed for the reasons made of record.

### **Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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<sup>1</sup> Cited on PTO Form 892 on 21 September 2007.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/

Primary Examiner, Art Unit 1614